1. \*Gender:

[ ] Male

[ ] Female

[ ] Unknown

[ ] Unspecified

[ ]  Not reported

1. \*Date of Birth:
2. \*Ethnicity: (“X” ONLY one with which you MOST CLOSELY identify)

[ ] Hispanic or Latino

[ ] Unknown

[ ] Not Hispanic or Latino

[ ] Not Reported

1. \*Race (Mark all those with which you identify):

[ ] American Indian or Alaska Native

[ ] White

[ ] Asian

[ ] Unknown

[ ] Black or African-American

[ ] Not Reported

[ ] Native Hawaiian or Other Pacific Islander

1. Language:

[ ] English (eng)

[ ] Spanish (spa)

[ ] German (ger)

[ ] Chinese (chi)

[ ] French/Creole (cpf)

[ ] Arabic (ara)

[ ] Russian (rus)

[ ] Italian (ita)

[ ] Polish (pol)

[ ] Other, specify:

1. Country of Residence:

[ ] USA (US)

[ ] Canada (CA)

[ ] United Kingdom (GB)

[ ] Mexico (MX)

[ ] Australia (AU)

[ ] Other, specify:

Zip Code (First 3 digits ONLY):

\*Element is classified as Core

## General Instructions

This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. ([NIH Guideline on The Inclusion of Women and Minorities](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm)) NIH has chosen to continue the use of these definitions because they allow comparisons across many national data bases, especially national health data bases. Therefore, the racial and ethnic categories included on the CRF should be used as basic guidance, cognizant of the distinction based on cultural heritage.

## Specific Instructions

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

Responses to the demographic elements should be obtained from self-report when possible.

* **Gender type** – Choose one.
* **Date of birth** – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
* **Ethnicity** – Choose only one with which the participant/ subject most closely identifies.
* **Race** – Choose all those with which the participant/ subject identifies.
* **Language(s) fully fluent** – Choose all that apply.
* **Country of residence** – Choose one.
* **First 3 digits of zip code** – This is an optional field, if this information is not provided enter 000.
* Gender type – Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically. The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 (<http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm>)
	+ Unspecified is defined as Undifferentiated/Indeterminant/Intersex
* Date of birth – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
* Ethnicity – Choose only one with which the participant/ subject most closely identifies.
* Race – Choose all that apply. Response is obtained by report of the participant/subject or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race in order to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. (http://grants.nih.gov/grants/funding/women\_min/guidelines\_update.htm) Collection of Race and Ethnicity Data in Clinical Trials (FDA, September 2005 - http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm)